

REMARKS

I. Status of the Application

Claims 1-17 were originally filed in the present application. In the Restriction Requirement mailed August 25, 2004, the Examiner restricted claims 1-17 into the following three groups:

- I. Claims 1-12 and 14-16, drawn to an apparatus, classified in class 422, subclass 57;
- II. Claim 13, drawn to a method, classified in class 435, subclass 326; and
- III. Claim 17, drawn to a compound, classified in class 435, subclass 7.1.

Applicants elected, without traverse, to prosecute the claims of Group I, and cancelled Claims 13 and 17. In the Office Action mailed October 21, 2004, the Examiner rejected Claims 1-12, 14-16. Applicants herein cancel Claims 1-12, 14-16 in order to further define the present invention and to further the Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000)), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the cancelled (or similar) claims in the future. Claims 18-31 have been added. As such, Claims 18-31 are pending in the application.

Although Claim 14 has been cancelled, new Claim 18 has been added that is an amended form of cancelled claim 14. The Examiner rejected Claim 14 under 35 U.S.C. §112 as allegedly being vague and confusing, §102(b) as allegedly being anticipated by Kornguth et al, and §103 as allegedly being unpatentable in view of prior art references. Thus, in an effort to expedite prosecution of the application, the Examiner's rejection of cancelled Claim 14 is addressed in the context of newly added Claim 18.

II. The Claims Are Definite and Supported by an Adequate Written Description

Claims 18-31 have been added. Support for these claims may be found in the specification at page 5, last paragraph, through page 7, among other places. In particular, support for "whole cell solution", "lysed cell solution", and "subcellular fragment

solution" are found in the specification on page 9, line 28 to page 10, line 13; and support for "cellular product" is found in the specification at page 3, lines 7-26.

Accordingly, it is respectfully submitted that Claims 18-31 are supported by an adequate written description and that the Examiner's arguments are moot.

III. The Claims are Not Anticipated by Kornguth *et al.*

The Examiner rejected Claim 14 under 35 U.S.C. §102(b) as allegedly being anticipated by Kornguth *et al.* (U.S. Pat. No. 5,629,213). Although Claim 14 has been cancelled, new Claim 18 has been added that is an amended form of cancelled claim 14. Thus, in an effort to expedite prosecution of the application, the Examiner's rejection of cancelled Claim 14 is addressed in the context of newly added Claim 18.

Applicant asserts that a rejection of claim 18 under 35 U.S.C. 102 as being anticipated by Kornguth *et al.* would be improper. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."¹ The cited reference does not teach nor possess all of the elements of the claimed invention. Thus, Claim 18, and claims dependent thereon, can not be anticipated by the prior art.

At page 5, second paragraph of the Office Action, the Examiner admits that Kornguth *et al.* teach "a SPR biosensor system with an ultra-thin organic film patterned on an array of islands on a noble metal surface, wherein each island may comprise a slightly different organic film for detection of a single analyte or the detection of multiple analytes ... wherein the organic film may comprise a protein such as biotin or receptors and nucleic acids, and wherein the organic film is able to detect epitopes on viruses and bacteria." However, the reference does not teach the use of its SPR systems for the analysis of solutions containing whole cells, e.g., where the cell itself can serve as the analyte. As Kornguth *et al.* does not disclose all elements of the claimed invention, Claim 18, and claims dependent thereon, cannot not be anticipated by Kornguth *et al.* under 35 U.S.C. 102.

¹ *Verdegaal Bros. v Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

IV. The Claims are Not Obvious

The Examiner rejected Claim 14 under 35 U.S.C. §103 as allegedly being unpatentable in view of prior art references. Although Claim 14 has been cancelled, new Claim 18 has been added that is an amended form of cancelled claim 14. Thus, in an effort to expedite prosecution of the application, the Examiner's rejection of cancelled Claim 14 is addressed in the context of newly added Claim 18.

The Examiner rejected Claim 14 under 35 U.S.C. §103 as allegedly being unpatentable over Kornguth *et al.* (U.S. Pat. No. 5,629,213) in view of Magnani (U.S. Pat. No. 5,965,457), Roos *et al.* (U.S. Pat. No. 6,008,893), Cantor *et al.* (U.S. Pat. No. 6,007,987), or Treuter *et al.* (JBC, 274(10), [1999]). Applicant respectfully disagrees.

A *prima facie* case of obviousness requires the Examiner to provide a reference(s) which (a) discloses all of the elements of the claimed invention, (b) suggests or motivates one skilled in the art to combine the claimed elements to produce the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness and without more entitles the Applicant to allowance of the claims in issue.² Applicant respectfully submits that the cited references are not properly combined and do not provide a reasonable expectation of success.

There is no basis for combining the Korngluth and Magnani references. The presently claimed invention is directed to a system wherein whole cells can be bound to an array on a solid surface. Thus, in order to properly combine the references, the references themselves would need to teach or suggest that an array could be used for this purpose. The Examiner has pointed to no such teaching or suggestion.

Instead of providing a teaching or suggestion to combine, the Examiner states that "It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al, with a sample of bone marrow containing a mixture of bone marrow stem cells and T lymphocytes, wherein a purification process using antibodies to CD34 antigen is used to isolate the stem cells in the sample, as taught by Magnani, in order to provide a biological source of bone marrow stem cells to

² See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

repopulate the bone marrow of a cancer patient after ablative treatment.” This statement is an example of conclusory reasoning, based only on hindsight reconstruction of the claimed invention.

A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**³

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability. 'Common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.⁴

In the present rejection, the Examiner's analysis is conclusory because the Examiner has merely stated what the reference technically teaches (i.e., purification of stem cells by binding to an antibody) and then states “it would have been obvious to one of ordinary skill in the art” to modify Kornguth with this teaching. This is precisely the type of the rejection that the Federal Circuit has forbidden in *In re Lee*. The **only reason** provided by the Examiner to modify Kornguth is that “it would have been obvious to one of skill in the art.” There is no “objective evidence of record” as required by the Federal Circuit. This is not surprising, since Kornguth and Magnani are directed to completely different technologies, one for the detection of analytes and the other for purification of cells for

³ *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

⁴ *Id.* at 1344-1345.

therapeutic uses. Neither reference, alone or combined, teaches or suggests the use of arrays to analyze solutions of whole cells.

The Examiner's reasonable expectation of success argument fails for the same reason. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness.⁵ The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added). There is no reasonable expectation of success because there was no way to predict whether arrays could be used to bind cells in a solution. Thus, the Examiner has improperly applied an "obvious to experiment" standard.

It is believed that these arguments effectively rebut the Examiner's obviousness rejections because all of the claims now contain the "whole cell solution" limitation. Thus, combination with the other references cited for obviousness purposes, such as Ruth, Cantor and Treuter, does not cure the defects noted above. For this reason, the rejections over these references are not addressed independently. Nevertheless, Applicants do not believe that these references establish a prima facie of obviousness either, and Applicant reserves the right to address the rejections made over these references in the future if the need arises. Nothing in this response shall be taken as an admission that the Examiner's statements about these references are correct or that these references are combinable with the references discussed in detail above for obviousness purposes.

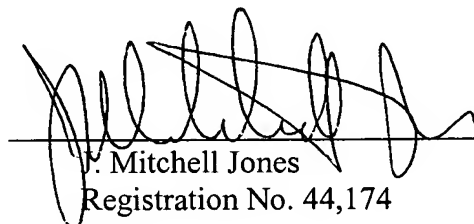
⁵

In re Dow Chemical, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicant's claims as amended should be passed to allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, Applicant encourages the Examiner to call the undersigned collect at 608-218-6900.

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